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10/537,583	12/14/2005	Katherine Ann Vousden	2543-1-041PCT/US	4893

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT	PAPER NUMBER
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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,583	Applicant(s) VOUSDEN, KATHERINE ANN	
	Examiner Oluwatosin Ogunbiyi	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 5/11/2007 has been entered into the record. Claims 1-11 and 14-22 were originally pending. Claims 14-16 and 18-22 were withdrawn. Claims 1-11 and 17 were examined. Claims 2-7,9-13 and 17 have been cancelled. Claims 1 and 8 have been amended and are now under examination.

Objection to the Specification

Acknowledgement is made of amendments to the specification to remove embedded hyperlinks.

Objection to the Claims

Claims 2,4,7 and 11 were objected to as set forth in the previous office action. Applicant has canceled claims 2,4,7 and 11.

Rejections Withdrawn

1. Rejection of claim 11 under 35 USC 101 as being drawn to non-statutory subject matter is withdrawn in view of cancellation of the claim.
2. Rejection of claims 2, 7,9,10 and 11 under 35 USC 112, first paragraph as failing to comply with the written description requirement is withdrawn in view of Applicant's cancellation of the claims.
3. Rejection of claims 1-3,8-11 and 17 under 35 USC 112, first paragraph as failing to comply with the enablement requirement is withdrawn in view of the amendment to claims 1 and 8 and the cancellation of claims 2-3,9-11 and 17.
4. Rejection of claims 2-3, 9 and 17 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is withdrawn in view of the cancellation of the claims.
5. Rejection of claims 1-2 and 9 under 35 USC 102(b) as being anticipated by Sternbach et al. 1976. Eur. J. Biochem, 67:215-221 is withdrawn in view of the cancellation of claims 2 and 9 and the amendment to claim 1.
6. Rejection of claims 1-2 and 8 under 35 USC 102(b) as being anticipated by Bradley et al. WO 02/02784A1 is withdrawn in view of the cancellation of claim 2 and the amendment to claims 1 and 8.
7. Rejection of claims 1-2 and 9 under 35 USC 102(b) as being anticipated by Kroger et al. 1979 Eur. J. Biochem, 95:341-348 is withdrawn in view of the cancellation of claims 2 and 9 and the amendment to claim 1.

Art Unit: 1645

8. Rejection of claims 1-2, 9 and 10 under 35 USC 102(b) as being anticipated by Navarro et al. 1991, Italian Journal of Biochemistry, 40:295-303 is withdrawn in view of the cancellation of claims 2, 9 and 10 and the amendment to claim 1.
9. Rejection of claims 4 and 7 under 35 USC 102(b) as being anticipated by Deng et al, 2000, Yeast 16:945-952 is withdrawn in view of the cancellation of the claims.
10. Rejection of claims 4,6 and 7 under 35 USC 102(b) as being anticipated by Wolfe et al. 1996, Journal of Biological Chemistry, 271:4679-4686 is withdrawn in view of the cancellation of the claims.
11. Rejection of claims 4,6, 7 and 11 under 35 USC 102(b) as being anticipated by Hanic-Joyce. 2002 (published online 10/31/2002, Yeast, 19:1399-1411 is withdrawn in view of the cancellation of the claims.
12. Rejection of claims 4,6 and 7 under 35 USC 102(b) as being anticipated by Chen et al. Journal of Biological Chemistry, 1991, 267:14879-14883 is withdrawn in view of the cancellation of the claims.
13. Rejection of claims 4,6 and 7 under 35 USC 102(b) as being anticipated by Aebi et al. Journal of Biological Chemistry, 1990, 265:16216-16220 is withdrawn in view of the cancellation of the claims.
14. Rejection of claim 5 under 35 USC 103(a) as being anticipated by unpatentable over Hanic-Joyce et al in view of Backen et al. 2000, Yeast, 16:1121-1129 is withdrawn in view of the cancellation of the claim.

Art Unit: 1645

15. Rejection of claims 2 and 7 under 35 USC 103(a) as being anticipated by unpatentable over Wolfe et al in view of Invitrogen Catalog, 2000, p. vii and p.79 is withdrawn in view of the cancellation of the claims.

New Objections Based on Amendment.

Claim 8 is objected to due to a grammatical error. *Candida albicans* is misspelled.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn a method of screening or testing for candidate anti-fungal compounds that impair *Candida albicans* ATP (CTP): tRNA nucleotidyltransferase enzyme (CCA1) activity comprising:

- a) providing a *C. albicans* cell wherein the cell expresses *Candida albicans* ATP (CTP): tRNA nucleotidyltransferase enzyme (CCA1) under the control of a heterologous promoter
- (b) providing one or more candidate compounds;
- c) contacting said *Candida albicans* cell(s) with said one or more candidate compounds;
- d) inducing said promoter;
- e) determining the effect of the candidate compound on activity by assessing the effect on growth or viability of said cells; and
- f) comparing said activity to the activity of a sample of the *C. albicans* cell(s) wherein said promoter is repressed.

The nature of the invention as set forth supra involves screening or testing for an anti-fungal compound that impairs *C. albicans* CCA1 by determining the effect of said compound on growth or viability of *C. albicans* cells expressing *C. albicans* CCA1.

The specification on p.2 line 38 teaches that CCA1 is an essential protein for the fungal species *Candida*. Example 4 on p. 10 gives a demonstration of CCA1 as an essential gene product in *Candida albicans*. A *Candida albicans* strain with one copy of the CCA1 gene under the control of tetracycline inducible promoter expresses CCA1 under strong induction i.e. without tetracycline and does not express CCA1 under tight

Art Unit: 1645

repression i.e. with tetracycline. Under CCA1 expression, there is cell growth and no significant growth was observed when CCA1 is repressed (p. 11 example 4.2).

However, this in vivo assay system for screening or testing for an anti-fungal compound that impairs *C. albicans* CCA1 and that described in the claim does not take into account that there are more than one essential genes in *C. albicans* (Song et al. Microbiology (2003), 149:219-259, Veses et al. Eukaryotic Cell (2005), p. 1088-1101, Bruno et al. Trends in Microbiology (2004) 12: 157-161, p.159, table 2) and also a compound may have multiple targets including CCA1. The claim requires contacting a candidate compound with a *Candida albicans* cell(s) expressing CCA1. If negative effects on growth or viability are seen in said cell(s), how does one of skill in the art determine that said negative effect is due to impairment of CCA1 by the candidate compound? The specification and the claim does not correlate impairment of growth or viability with the direct impairment with CCA1. The assay described in the specification and claim does not provide any guidance or direction as to how to rule out the effects of such compound on other essential genes in said *C. albicans* expressing CCA1.

For example, Onishi et al (Feb. 2000, Antimicrobial Agents and Chemotherapy p. 368-377 cited in previous action.) teaches a screen for in vitro antifungal activity of several compounds by a growth inhibition assay (page 369 column 1 materials and methods and table 1) and then the compounds were evaluated to determine whether said compounds were direct inhibitors of the enzyme by measuring the enzyme's activity in the presence of said compounds (page 370 column 2 first full paragraph, page 373 column 1 - 2 and table 4).

Art Unit: 1645

Assessing inhibition of growth does not provide any knowledge about the effect of the compound on CCA1 activity as claimed because as mentioned above a compound may have more than one target in said *C. albicans* expressing CCA1 including CCA1. Furthermore, an anti-fungal compound has many different activities (see Ghannoum et al. 1999. Clinical Microbiology Reviews, p. 501-517 for different mode of actions of some anti-fungal compounds, cited in previous office action) and these compounds would inhibit growth but do not have to impair activity of CCA1. As such, impairment of growth is not directly correlated with impairment of CCA1 activity in the method of screening set forth in the claim. One of skill would not reasonably conclude from the claim that a compound that impairs CCA1 activity is solely responsible for impairing growth in a *C. albicans* cell expressing *C. albicans* CCA1.

In view of the above, it would require undue experimentation for the skilled artisan to use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

The claim is drawn to a method of screening or testing for candidate anti-fungal compounds that impair *Candida albicans* ATP(CTP):tRNA nucleotidyltransferase enzyme (CCA1) activity comprising:

- a) providing fungal *Candida albicans* CCA 1;
- b) providing one or more candidate compounds;
- c) contacting said CCA 1 with said one or more candidate compounds; and
- d) determining the interaction of the candidate compound with said activity of CCA 1.

Step (d) as recited in the claim is confusing. The recitation of *determining the interaction of a candidate compound with said activity of CCA1* is unclear. Can a compound interact with activity? Since the preamble of the claim is a *method of screening or testing for candidate anti-fungal compounds that impair Candida albicans ATP(CTP):tRNA nucleotidyltransferase enzyme (CCA1) activity*, it is suggested that Applicant amend step (d) to recite *determining the ability of the candidate compound to inhibit CCA1 activity*.

Status of Claims

Claims 1 and 8 are rejected. Claims 14-16 and 18-22 are withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1645

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Oluwatosin Ogunbiyi

Examiner

Art Unit 1645


PATRICIA A. DUFFY
PRIMARY EXAMINER